

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2103325	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Ramon Ramos, Md	Street Address, City, State 412 Us Hwy 80, Pooler, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A proficiency testing desk review was completed on November 6, 2019. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three out five PT events (Event 1 of 2018, Events 1 & 2 of 2019),

	resulting in the second unsuccessful occurrence for hematology #0760, RBC #0775, and HCT #0785. (Refer to D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three of five PT events (Event 1 of 2018, Events 1 & 2 of 2019), resulting in the second unsuccessful occurrence for hematology #0760, red blood cell count (RBC) #0775, and hematocrit (HCT) #0785. The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the specialty of hematology #0760 on Event 1 of 2018 with a score of 60%, Event 1 of 2019 with a score of 71%, and Event 2 of 2019 with 0%. The laboratory failed analyte RBC #0775 on Event 1 of 2018 with a score of 20%, Event 1 of 2019 with a score of 60%, and Event 2 of 2019 with a score of 0%. Also, the laboratory failed analyte HCT #0785 on Event 1 of 2018 with a score of 0%, Event 1 of 2019 with a score of 60%, and Event 2 of 2019 with a score of 0%. 2. The American Academy of Family Physicians (AAFP) criteria for acceptable performance for the specialty of Hematology is a score of 80%. 3. Desk review of the laboratory's proficiency testing reports from AAFP confirms the laboratory failed hematology, RBC, and HCT on Event 3 of 2017 and Event 1 of 2018 resulting in the first unsuccessful performance and reveals the laboratory also failed Events 1 & 2 of 2019 resulting in the second unsuccessful performance in the specialty of hematology.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three out five PT events (Event 1 of 2018, Events 1 & 2 of 2019), resulting in the second unsuccessful occurrence for hematology #0760, RBC #0775, and HCT #0785. (Refer to D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 & 153 and the laboratory's 2017, 2018 and 2019 proficiency testing (PT) evaluation reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance for three of five proficiency testing events (Event 1 of 2018, Events 1 & 2 of 2019), resulting in the second unsuccessful occurrence for hematology #0760, red blood cell count (RBC) #0775, and hematocrit (HCT) #0785. 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the specialty of hematology #0760 on Event 1 of 2018 with a score of 60%, Event 1 of 2019 with a score of 71%, and Event 2 of 2019 with 0%. The laboratory failed analyte RBC #0775 on Event 1 of 2018 with a score of 20%, Event 1 of 2019 with a score of 60%, and Event 2 of 2019 with a score of 0%. Also, the laboratory failed analyte HCT #0785 on Event 1 of 2018 with a score of 0%, Event 1 of 2019 with a score of 60%, and Event 2 of 2019 with a score of 0%. 2. The American Academy of Family Physicians (AAFP) criteria for acceptable performance for the specialty of Hematology is a score of 80%. 3. Desk review of the laboratory's proficiency testing reports from AAFP confirms the laboratory failed hematology, RBC, and HCT on Event 3 of 2017 and Event 1 of 2018 resulting in the first unsuccessful performance and reveals the laboratory also failed Events 1 & 2 of 2019 resulting in the second unsuccessful performance in the specialty of hematology.